

REMARKS/ARGUMENTS

Applicant is grateful for the opportunity to interview the present case with Examiners on 26 June 2008. A summary of that interview was Examiner found the arguments presented by Applicant to distinguish Eschel were persuasive. Examiner has provided additional references to Applicant with a request for due consideration. Those references are discussed herein.

Examiner requested Applicant review US Patent 5,382,885 ('885) issued to Salcudean et al. On review, the '885 reference provides for a robotic arm for use in surgical procedures. The robotic arm has several levels of control, allowing a user to have both macro and micro motor control over the movement and positioning of the arm. The arm is designed for surgical procedures, however the reference does not teach what type of medical instrument in particular the arm is designed to be used with. Applicant believes the arm of the '885 reference has very little in common with the subject matter pending before the Examiner in the present case. The '885 lacks any description or operation of a therapy head, water circulation system or data chip. Because the '885 reference restricts itself to the elements of a mechanical arm, Applicant does not believe this reference represents an obstacle for patentability of the claims pending in the present case.

Examiner has also requested Applicant review US Patent 6,007,499 ('499) issued to Martin et al. The '499 reference teaches a high intensity focused ultrasound (HIFU) transducer attached to an arm for use in a surgical procedure. The arm in the '499 reference is not a robotic arm, but a member of a clamp or tweezers like device. The apparatus in the '499 reference has two embodiments. In one embodiment, there is a device having two arms. One arm is used underneath an organ (e.g. the liver) while the other arm goes over the organ. The top arm has a HIFU transducer, and ultrasound energy is broadcast into the organ for disease state therapy (like cancer treatment). The second embodiment is for the transducer to be placed on the end of a straight arm, like a handle. The device is then placed adjacent to a tissue needing treatment, and HIFU energy is broadcast out of the therapy unit, against an acoustic reflector, to cause the ultrasound energy to focus into the desired tissue at a 90 degree angle from the axis of the

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transducer. The '499 reference has no robotic arm, no water circulation or therapy head, no data chip, and lacks many of the features of the pending claims in the present invention. There is virtually no similarity between the '499 reference physically, and the device described in the pending claims.

The third reference Examiner requested Applicant review is US Patent 6,846,290 ('290) issued to Lizzi et al. This reference provides many of the same features as the present application and is probably the closest among the references Examiner provided to Applicant in the interview. As such, please permit this detailed analysis and comparison.

First, the '290 reference is designed to provide an ultrasound transducer for use in therapeutic applications which is external to the patient body. E.G. this is not a surgical device, it is primarily designed to be used as non-invasive therapy device. The '290 device uses both a diagnostic and therapeutic transducer. The diagnostic transducer transmits along the same axis as the therapy transducer, so the diagnostic device can track the precise location of the focal zone of the therapeutic transducer. There is an "apparatus" for transporting the transducer (See Fig. 5, '290), however it is defined simply as a frame having tracks for moving the transducer. There is a motor for moving the transducer along the tracks, however this is strictly in a motion along the tracks.

Second, the use of the device is such that the diagnostic transducer tracks the position of the focal zone of the therapeutic transducer while the therapy transducer is "on." As a patient breaths, the focal zone may change in depth. Depth changes may move the desired focal zone away from or closer to the therapy transducer, which is undesirable in the application of the '290 invention. When the diagnostic transducer detects depth changes, a corresponding depth change is made in the therapy device using a phase change in the therapy transducer (see Figs. 3 and 4, '290). This process for adjusting the depth is theoretically very precise, assuming the computer controlling the system can respond in real time.

The main focus of the transducer usage is a vertical up and down tracking of locations of the focal zone. This is primarily important where the target tissue is deep under the patient skin line. When a person breaths, their skin moves in and out, while their internal organs

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remain relatively stationary. Thus if a transducer is focused deep, depth compensation becomes more important.

Applicant now compares the '290 reference to the present application. The '499 does not provide any sort of robotic arm, nor is there a water circulation system, data chip or therapy head. The present application has a therapy head having a diagnostic transducer (used for imaging) and a therapy transducer (used for therapy), however the two transducers do not work together to achieve a single result in the same way the '499 reference uses them. In the present application, the therapy transducer is concerned with station keeping, that is holding the same position on the patient's skin. The location and depth of the focal zone is not tied to fixed position in the body but a moving position near the skin. Said another way, the desired target of the present claims are near the skin, so as a person breathes, the relative position of the focal zone does not change, however the compensation of the robotic arm (with its position sensors) is needed to keep the therapy head moving with the skin. So while the desire to maintain the position is similar in the prior art and the present case, the manner of obtaining the positioning is uniquely suited only for each reference. Specifically, the position sensor and robotic arm of the present application cannot achieve the desired result in the '499 reference. The teaching of the '499 reference cannot be used in the present application to achieve Applicant's desired results. As such, Applicant believes the '290 reference is not an obstacle to patentability of the present application. The '290 reference neither anticipates the present claimed invention, nor does it combine with any of the present references to make the present application (see below).

The fourth reference is US Patent 4,484,569 ('569) to Driller et al. Driller describes an ultrasound apparatus for use on human or animal eyes. The device described has the similarities of a therapy transducer, and a light source for providing spot illumination through the central bore of the transducer. There is a housing provided that has water or other fluid within it and which is used to provide coupling from the transducer to the surface of the eye. There is a thin film at the tip of the apparatus to allow ultrasound and light energy to pass through while holding the fluid within. The '569 reference differs substantially from the pending claimed subject matter in that there is no robotic arm, and no position sensor for providing feed back to the robotic arm. In addition, the water in the '569 device is static, there is no circulation system.

There is also no data chip in the '569 reference for identifying one or more types of therapy heads.

Finally Examiner requested Applicant review US Patent Application 10/256,681, ('681) US Publication number 2003/0050654 A1 by Whitman et al. The Whitman reference teaches an electromechanical surgical device for providing higher torque to surgical instruments. The '681 reference teaches using motors within a larger base unit allow for more powerful motors to be used, and that allows for more torque to be transferred up a flexible shaft (part 20 in the drawings of the '681 reference). The '681 reference is primarily concerned with the base unit and the ability to transfer mechanical energy through the flexible shaft. Further, the '681 specifically teaches that having motors closer to the handle (the surgical end) of a device is a disadvantage. The '681 reference can be readily distinguished because the present application has a motorized ultrasound transducer array inside the therapy head, in direct conflict with the teaching of the '681 reference.

Examiner's request for Applicant to review the above references also invites an analysis for any obvious combination issues under 35 USC §103(a). Three of the references are for surgical devices ('681, '885 and '499). These reference are all designed for use in invasive surgical applications. Martin ('499) teaches the tweezers like device or the simple handle transducer with a reflector. Whitman ('681) and Salcudean ('885) both teach about surgical members or arms, but lack any discussion of an effector unit on the end, like a therapy head. There is no reason to combine Lizzi ('290) with either arm. Enhanced torque would be counterproductive for the '290 application, and enhanced fine motor control of a transducer using diagnostic imaging feedback would be redundant and useless. Similarly there is no need to connect the arms above with the device of Driller ('569) since the Driller device is designed to rest on the surface of the eye. Any torque or fine motor control would again be counterproductive.

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CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,

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